REMARKS

Claims 1-17 are pending in this application. Claims 1, 10, and 17 have been amended.

Amendments to the Claims

Applicant amends independent claim 1 to specify that energy is transmitted through the housing of the ablation instrument to ablate tissue at a target site. Support for this amendment can be found throughout the specification, for example, at page 11, lines 12-17. Claims 10 and 17 are amended to specify that the ablation element is positioned within the lumen of the housing and energy is transmitted through the housing to ablate tissue at a target site. Support for these amendments can be found throughout the specification, for example, at page 11, lines 12-17. No new matter is added.

Continuity Data

The Examiner has indicated that the continuity data in the application is inconsistent with the continuity data available on PAIR. A Request for Corrected Filing Receipt has been filed concurrently with this Amendment and Response to clarify that U.S. Patent Application Serial No. 09/382,615 represents a separate line of continuation.

Rejections under 35 U.S.C. § 102

U.S. Patent No. 5,910,129 to Koblish et al.

Claims 1-17 were rejected under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 5,910,129 to Koblish et al. (hereinafter "Koblish"). Based on the amendments and the following remarks, Applicant respectfully requests reconsideration and withdrawal of the anticipatory rejection.

Independent claim 1, as amended, recites a surgical ablation instrument including a housing, an ablation element, and a fluid channel within the housing. The housing has a longitudinal lumen, and the distal end of the housing is sufficiently flexible to be bent into a loop

configuration. The ablation element is *disposable within* the lumen of the housing for transmitting energy *through the housing* to ablate tissue at a target site.

Koblish fails to teach or even suggest an ablation element that is disposable within a lumen of a housing for transmitting energy through the housing to ablate tissue at a target site, as required by independent claim 1. Koblish discloses a flexible ablation catheter assembly for transferring ablation energy by ionic transport. As shown in Figures 36 and 37 of Koblish, the catheter has a center support lumen (370) enveloped by a porous material (364). The lumen (370) includes spaced-apart electrodes (372) and apertures (374) along its length. In use, fluid is introduced through the lumen (370) and passes through the apertures (374) to ablate tissue. As explained by Koblish, "[t]he porous material 364 has pores capable of allowing transport of ions contained in the fluid through the material 364 and into contact with tissue." (Koblish column 21, lines 63-65). Thus, the "ablation element" of Koblish includes both the electrodes disposed within the porous sleeve and the ionic fluid which transfers the ablation energy from the electrodes to the targeted tissue. In other words, the ablation element taught by Koblish is disposed both within the porous sleeve and outside of it. Koblish fails to disclose an ablation instrument having a ablation element disposable *within* a lumen of a housing for transmitting energy *through* the housing, as required by independent claim 1. Accordingly, independent claim 1, as well as claims 2-9 which depend directly or indirectly therefrom, distinguish over Koblish and represent allowable subject matter.

Independent claims 10 and 17, as amended, relate to a method for ablating a target tissue including: providing a surgical ablation instrument having a housing with a proximal end, a distal end and a longitudinal lumen extending therebetween, the distal end of the elongate housing being sufficiently flexible to be bent into a loop configuration, an ablation element disposed within the lumen of the housing *for transmitting energy through the housing* to ablate tissue at a target site, and a fluid channel within the housing for introducing fluid to the ablation element during delivery of the ablation energy; positioning the surgical ablation instrument proximate to a predetermined tissue site; *positioning the ablation element within the lumen of the housing*; and transmitting ablative energy *through* the distal end of the housing through the

ablation element, such that the target tissue is ablated, coagulated or phototherapeutically modulated without damaging surrounding tissue.

Koblish fails to teach or even suggest a method for ablating a target tissue including positioning an ablation element *within* a lumen of a housing for transmitting energy *through* the housing to ablate tissue at a target site, as required by independent claims 10 and 17. As explained above, Koblish discloses a method for ablating tissue using a flexible ablation catheter assembly to transfer ablation energy by ionic transport. The ablation structure (360) includes a center support lumen (370) enveloped by a porous material (364). The lumen (370) includes spaced-apart electrodes (372) and apertures (374) along its length. In use, the electrode structure (360) is *advanced* from a sheath (36), and fluid flows through the lumen (370) and exits through the apertures (374) and porous material (364) to ablate the targeted tissue. As indicated above, the "ablation element" disclosed by Koblish includes both the electrodes and the ionic fluid. Thus, the ablation element taught by Koblish is disposed both within the porous sleeve and outside of it. Koblish fails to teach *positioning* the ablation element *within* a lumen of a housing and transmitting energy *through* that housing, as required by claims 10 and 17. Accordingly, independent claims 10 and 17, as well as claims 11-16 which depend directly or indirectly therefrom, distinguish over Koblish and represent allowable subject matter.

U.S. Patent No. 6,325,797 to Stewart et al.

Claims 1, 3, 6-10, and 15-17 were rejected under 35 U.S.C. § 102(e) as being anticipated by U.S. Patent No. 6,325,797 to Stewart et al. (hereinafter "Stewart"). Based on the amendments and the following remarks, Applicant respectfully requests reconsideration and withdrawal of the anticipatory rejection.

As explained above, independent claim 1, as amended, recites a surgical ablation instrument including an ablation element that is *disposable within* a lumen of a housing for transmitting energy *through the housing* to ablate tissue at a target site, and a fluid channel within the housing for introducing fluid to the ablation element during delivery of the ablation energy. Stewart fails to teach or even suggest an ablation element with such features. Stewart discloses an ablation catheter assembly having a catheter body (22) with electrodes (26) disposed

thereon. The electrodes (26) are "disposed along a portion of the catheter body 22". (Stewart col. 5, lines 30-31). The Examiner asserts that the electrodes (26) are inherently disposed within the lumen of the housing because the inner wiring must extend through the lumen. While the wiring may extend through the lumen, the electrodes are not contained within the lumen and are, in fact, in direct contact with the targeted tissue. (Stewart column 8, lines 6-7). Thus, Stewart does not teach or even suggest that the electrodes (26) are *disposable within* a housing for transmitting energy *through the housing* to ablate tissue at a target site, as required by claim 1.

Moreover, Stewart fails to teach or even suggest a fluid channel within a housing for introducing fluid to an ablation element during delivery of the ablation energy. The Examiner asserts that Stewart discloses such a feature at column 7, lines 1-3. However, Stewart merely states that, "[t]he electrodes 26 may be cooled by a separate source (not shown), such as a saline source." Stewart does not indicate that the fluid can be introduced through a channel formed in the housing. In fact, stating that the electrodes may be cooled by a "separate source" suggests that the fluid is not introduced via the ablation catheter, as required by claim 1. Accordingly, independent claim 1, as well as claims 2-9 which depend directly or indirectly therefrom, distinguish over Stewart and represent allowable subject matter.

Independent claims 10 and 17, as explained above, relate to a method for ablating a target tissue including *positioning an ablation element within a lumen of a housing* and transmitting energy *through that housing* to ablate tissue at a target site. Stewart fails to teach or even suggest a method for ablating tissue including such steps. Stewart discloses a method for ablating tissue including contacting targeted tissue with electrodes (26) disposed on a catheter body (22) and delivering ablative energy to the tissue via the electrodes (26). The electrodes (26) are spaced along the catheter body (22) and are in direct contact with the targeted tissue. (Stewart column 6, lines 62-64; column 8, lines 6-7). Stewart does not teach or even suggest positioning the electrodes (26) *within* a lumen of a housing and transmitting energy *through that housing* to ablate the targeted tissue, as required by claims 10 and 17. Accordingly, independent claims 10 and 17, as well as claims 11-16 which depend directly or indirectly therefrom, distinguish over Stewart and represent allowable subject matter.

Double Patenting Rejection

The Examiner rejects claims 1-17 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1 of copending Application No. 10/756,645, claim 1 of copending Application No. 10/756,660, claim 1 of U.S. Patent No. 6,558,375 (hereinafter "the '375 patent"), and claim 1 of U.S. Patent No. 6,676,656 (hereinafter "the '656 patent"). This application claims priority to U.S. Patent No. 6,558,375 and U.S. Patent No. 6,676,656. Applicant submits terminal disclaimers herewith, thereby obviating the basis for the rejections over the copending applications 10/756,645 and 10/756,660.

As explained in MPEP §804(II)(B)(1)(a), a one-way determination of obviousness is needed in resolving the issue of doubling patenting. In other words, the inquiry is whether the invention defined in a claim in the application would have been an obvious variation of the invention defined in a claim in the patent.

Claims 1-17 of the pending application are not obvious in view of claim 1 of the '375 patent. Claim 1 of the '375 patent recites a cardiac ablation instrument including a light transmitting optical fiber and a light diffusing element having a *toroidal* shape to emit an annular pattern of uniform radiation. In contrast, claim 1 of the pending application recites a surgical ablation instrument including a housing, an ablation element disposable within a lumen of the housing, and a *fluid channel* within the housing for introducing fluid to the ablation element during delivery of the ablation energy. Claim 1 of the '375 patent does not teach or even suggest a fluid channel disposed within the housing of the ablation instrument. Thus, claim 1 of the pending application, as well as claims 2-9 which depend directly or indirectly therefrom, are not obvious in view of claim 1 of the '375 patent. Independent claims 10 and 17 of the pending application recite *methods* for ablating a target tissue using an ablation instrument having a *fluid channel*. As explained above, claim 1 of the '375 patent does not teach or even suggest a fluid channel disposed within the housing of the ablation instrument. Moreover, during the prosecution of the '375 patent, a restriction requirement was issued indicating that the application included two patentably distinct species. The applicant of the '375 patent elected to pursue the species relating to the *device* claims. Thus, it was proper for the applicant to pursue

the non-elected *method* claims in a continuation application such as the pending application. Accordingly, claims 10 and 17 of the pending application, as well as claims 11-16 which depend directly or indirectly therefrom, are not obvious in view of claim 1 of the '375 patent.

Claims 1-17 of the pending application are not obvious in view of claim 1 of the '656 patent. Claim 1 of the '656 patent recites a method of ablating cardiac tissue including positioning a photoablation instrument around at least one pulmonary vein and activating a light delivery element disposed within a housing of the instrument to transmit tissue penetrating radiant energy through the housing. In contrast, claim 1 of the pending application recites a surgical ablation instrument including a housing, an ablation element disposable within a lumen of the housing, and a *fluid channel* within the housing for introducing fluid to the ablation element during delivery of the ablation energy. Claim 1 of the '656 patent does not teach or even suggest a fluid channel disposed within the housing of the ablation instrument. Moreover, during the prosecution of the '656 patent, a restriction requirement was issued indicating that the application included four patentably distinct species. The applicant of the '656 patent elected to pursue the species relating to the *method* claims. Thus, it was proper for the applicant to pursue the non-elected *device* claims in a continuation application such as the pending application. Thus, claim 1 of the pending application, as well as claims 2-9 which depend directly or indirectly therefrom, are not obvious in view of claim 1 of the '656 patent. Independent claims 10 and 17 of the pending application recite methods for ablating a target tissue using an ablation instrument having a *fluid channel*. As explained above, claim 1 of the '656 patent does not teach or even suggest a fluid channel disposed within the housing of the ablation instrument. Accordingly, claims 10 and 17 of the pending application, as well as claims 11-16 which depend directly or indirectly therefrom, are not obvious in view of claim 1 of the '656 patent.

CONCLUSION

In summary, the above-identified patent application has been amended and reconsideration is respectfully requested for all the reasons set forth above. In the event that the amendments and remarks are not deemed to overcome the grounds for rejection, the Examiner is kindly requested to telephone the undersigned representative to discuss any remaining issues.

Respectfully submitted,

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